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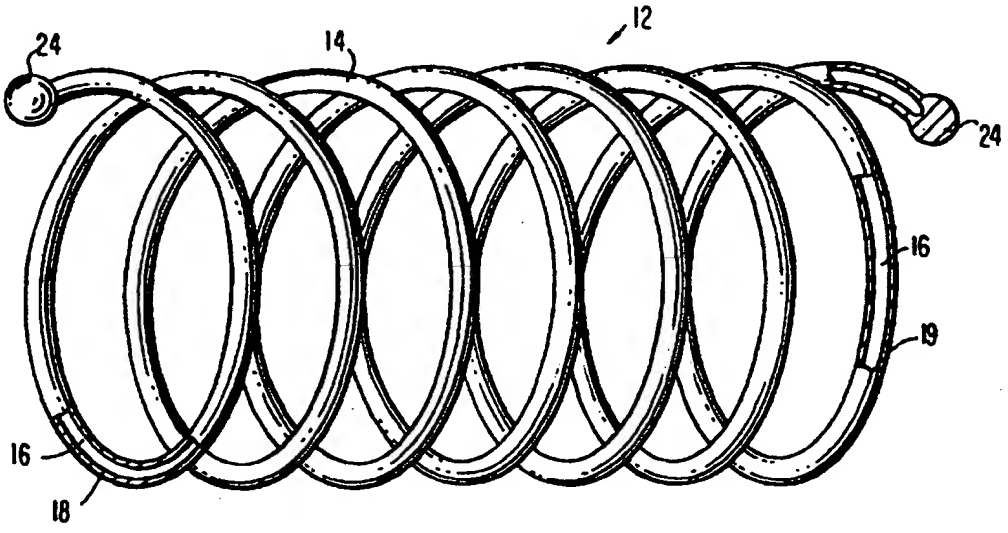


(57) Abstract

The invention concerns an implantable medical device comprised of tubular wire (14). In a preferred embodiment the invention comprises a stent or graft (12) formed from spirally wound, tubular wire (14), where the stent or graft is capable of being stressed prior to implantation to reduce the radius of curvature (5) of the wire to put the stent or graft (12) in a restrained condition.

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# HOLLOW STENT

## FIELD OF THE INVENTION

This invention is directed to a novel stent. More particularly, this invention is directed to a spiral, wound stent wherein the stent is comprised of a tubular material.

## BACKGROUND OF THE INVENTION

The use of implantable medical devices such as stents, grafts, or filters, is well known. While the shape or configuration of such devices may vary, they are typically comprised of solid wire.

For a more detailed description of the devices used in such structures, reference is made to: Simon, U.S. Pat. No. 4,425,908; Gianturco, U.S. Pat. No. 4,494,531; Dotter, U.S. Pat. No. 4,503,569; Balko et al., U.S. Pat. No. 4,512,338; Wallsten, U.S. Pat. No. 4,655,771; Fischell et al., U.S. Pat. No. 4,768,507; Kropf, U.S. Pat. No. 4,771,773; Regan, U.S. Pat. No. 4,795,458; Anderson et al., U.S. Pat. No. 4,813,925; Lindemann et al., U.S. Pat. No. 4,878,906; Hillstead, U.S. Pat. No. 4,913,141; Wilkoff, U.S. Pat. No. 4,990,155; Giantuneo et al., U.S. Pat. No. 5,035,706; Termin et al., U.S. Pat. No. 5,071,407; Burton et al., U.S. Pat. No. 5,078,720; Lee, U.S. Pat. No. 5,123,917; Hillstead, U.S. Pat. No. 5,135,536; McNamene et al., U.S. Pat. No. 5,147,370; Brenneman et al., U.S. Pat. No. 5,160,341; Tower, U.S. Pat. No. 5,161,547; Vince, U.S. Pat. No. 5,163,953; Pinchuk, U.S. Pat. No. 5,163,958; Heyn et al., U.S. Pat.

No. 5,201,757; Willard et al., U.S. Pat. No. 5,222,971; Morgentalen, U.S. Pat. No. 5,224,953; Pinchuk, U.S. Pat. No. 5,226,913; Lau et al., U.S. Pat. No. 5,242,399; Harada et al., U.S. Pat. No. 5,242,451; Inoue, U.S. Pat. No. 5,242,452; Garrison et al., U.S. Pat. No. 5,263,963; Schwertz et al., U.S. Pat. No. 5,282,823; Gianturco, U.S. Pat. No. 5,282,824; Boneau, U.S. Pat. No. 5,292,331; Stack et al., U.S. Pat No. 5,306,286; Song, U.S. Pat. No. 5,330,500; Sawyer, U.S. Pat. No. 5,344,425; Schnepp-Pesch et al., U.S. Pat. No. 5,254,309; Gernic et al., U.S. Pat. No. 5,354,310; Beyar et al., U.S. Pat. No. 5,372,600; and Medinol Ltd., PCT WO 94/20044, all of which are incorporated herein by reference.

In many of the products described above, the elastic property of the wire was used, by creating stress in the wire. The purpose for creating the stress was to reduce the stent's diameter and restrain the stent, before insertion of the device into a patient's body, whereupon, after the stent was inserted and the restraining means was removed, the stent expands and the stress releases.

When a solid wire is bent, for example, to reduce a device's external diameter, this causes tension and compression stresses in the wire. Because of the high deformation needed in some of the devices described in the references above, to reach minimal insertion profile, material having extremely high recoverable strain has been used. Examples of such material include Ni-Ti alloy known as nitinol. However, with the nitinol wire currently used there are limits as to how far the diameter of a stent can be decreased while staying within the same range of recoverable strain of the material.

## OBJECTS OF THIS INVENTION

It is an object of this invention to provide a novel stent.

It is also an object of this invention to provide a stent, graft, or filter comprised of material having desirable properties.

It is a further object of the inventor to provide a stent which can be constrained on a delivery catheter in an especially small diameter where the device is all in the same range of the recoverable strain of the material.

These and other objects of the invention will become more apparent from the discussion below.

## BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a partial, longitudinal cross-sectional view of an embodiment of the invention in unstressed condition;

Fig. 2 is a cross-section of the segment in Fig. 1;

Fig. 3 is a partial, longitudinal cross-sectional view of an embodiment of the invention under stress to reduce the diameter;

Fig. 4 is a cross-section of the segment in Fig. 3;

Fig. 5 is a perspective view, with partial sectional areas, of an embodiment of the invention; and

Fig. 6 is a partial cross-sectional view of an embodiment of the invention loaded on a delivery catheter.

## DETAILED DESCRIPTION OF THE INVENTION

Applicants have found that implantable medical devices such as stents, grafts, or filters, have improved properties if the wire from which such devices are made is hollow, i.e., tubular, rather than solid. When tubular wires with relatively thin walls are bent, they prove to be much more flexible during bending than would be expected based upon the behavior of solid wire. When solid wire is bent, the shape of the cross-section remains substantially unchanged, which means that fibers or elements of the wire are unevenly stressed. For example, elements of the wire opposite to the curvature would be strained, whereas elements on the radius of the curvature would be compressed. However, when tubular wire with a thin wall tube and having a circular cross-section is bent, the cross-section shape changes and the circular shape flattens and becomes elliptical, to apportion strain. It may, therefore, be concluded that the elements of the tube opposite to the natural axis are not strained in the manner as would be indicated for the ordinary bending of wire.

These are two main advantages of using tubular wire instead of solid wire:

1. With the same elasticity limit of the raw material, we can increase the relation between the radius of curvature before and after the bendings (before and after insertion into the body); and

2. The fact that the tube shape changes to elliptical after bending, helps to reduce the insertion diameter of the device.

The use of tubular members in medical devices is known. U.S. Pat. No. 4,813,925 describes a spiral ureteral stent with a lumen extending along the entire

length of the stent. The stent may be straightened by means of a wire stylet inserted into the lumen, to facilitate placement of the stent in the ureter. This means that to insert the device into the body, the radius of curvature of segments of the device is increased. In contrast, in the present invention, to insert the device into the body the radius of curvature is decreased without inserting any device into the inner lumen.

U.S. Pat. No. 5,234,456 describes a hydrophilic stent having a permeable or semi-permeable hollow wall with hydrophilic material disposed therein. The hydrophilic material swells upon introduction of a liquid into the hollow wall, to thereby achieve inflation of the stent. This use of a hollow wall is totally different from the present invention, as there is no stress in the stent wall due to being constrained and there is no reduction of stress in the stent wall during opening of the stent.

The theory of bending curved tubes is well known in the scientific literature. See, for example, "Strength of Material" Part I, by S. Timoshenko, Third Edition, pages 405-416, incorporated herein by reference.

In discussing the distribution of bending stresses in curved bars, it was assumed that the shape of the cross- section remains unchanged. Such an assumption is justifiable so long as the bar is solid, because the very small displacements in the plane of the cross-section due to lateral constriction and expansion have no substantial effect on the stress distribution. The condition is very different, however, in the case of a thin curved tube in bending, as discussed above. It is well known that curved tubes with comparatively thin walls prove to be more flexible during bending than would be expected from the usual theory of curved bars.

The invention can perhaps be better appreciated by reference to the drawings. A segment 1 of a tubular wire useful according to the invention is shown in Figs. 1 and 2. The segment has concave 3 and convex 4 surfaces that are unstressed. The radius of curvature 5 extends to the middle 7 of lumen 8. Segment 1 has a circular cross-section, as shown in Fig. 2.

Figs. 3 and 4 represent segment 1 under stress. Tensile forces at the convex surface 4 and compression forces at the concave surface 3, act upon the cross-sectional shape of segment 1. The result is that the radius of curvature 9 is smaller than radius of curvature 5, and the previously circular cross-section becomes elliptical, as shown in Fig. 4. This flattening of the cross-section affects the strain of the longitudinal elements of the tubular wire.

A very small flattening of the cross-section, produces a substantial decrease in the stresses at the outermost elements, as compared to the tensile stresses of a comparable solid wire. It may therefore be concluded that the elements of the tubular wire which are opposite to the tube axis, do not stress as would be expected according to the ordinary theory of bending of solid wire. This theory also is valid in the case of a tube of rectangular cross-section.

Fig. 5 is a perspective view of an embodiment of the invention in unstressed condition. The stent 12 comprises a spiral coil 14 of hollow, tubular material. The inner lumen 16 and coil 14 can be seen in partial cross-sectional areas 18 and 19.

When stent 12 is stressed to reduce its diameter, it can be positioned in stressed form on a catheter 20. The tubular material will assume an elliptical cross-section 22, as shown in Fig. 6. The balls 24 of stent 12 are

restrained, for example, on the outer surface of catheter 20 (not shown). Particulars regarding such restraining systems and the delivery of stents can be seen, for example, in U.S. Patents Nos. 5,246,445 and 5,372,600, both of which are incorporated herein by reference.

The tubular material useful according to the invention can comprise any suitable physiologically acceptable metallic material, such as stainless steel or an alloy. Especially useful are shape memory alloys, particularly nickel-titanium alloys known as nitinol. Also, the lumen of the tubular material may contain radiopaque material or pharmacological substances. The wall of the tubing may have one or more small or miniature openings so that such pharmacological substances can be dispensed. Each such opening could be from about 0.1 to 1 mm in actual or effective diameter.

The stents useful according to the invention can have shapes and sizes that will vary according to application. For example, for urological or cardiovascular use the tubular wire could have an o.d. of from about 0.3 to 1 mm, preferably about 0.4 to 0.6 mm, and an i.d. of from about 0.2 to 0.8 mm, preferably from about 0.4 to 0.5 mm. The outside diameter of the coiled stents could be from about 0.25 to 2.5 cm, with a coiled length of from about 10 to 80 mm. Stent preparation procedures are well known and are, for example, described in one or more of the above patents incorporated herein by reference.

The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other expedients known to those skilled in the art or disclosed herein, may be employed without departing from the spirit of the invention or the scope of the appended claims.

WE CLAIM:

1. An implantable medical device comprised of tubular wire.

2. The device of Claim 1, wherein the device is substantially cylindrical in shape.

3. The device of Claim 2, wherein the diameter of the device is reduced when the device is stressed and the diameter of the device returns to its original diameter when the stress is released.

4. The device of Claim 1, which is a stent, graft, or filter.

5. The device of Claim 1, wherein the wire comprises stainless steel or an alloy.

6. The device of Claim 5, wherein the alloy is a shape-memory alloy.

7. The device of Claim 6, wherein the shape-memory alloy is nitinol.

8. The device of Claim 1, wherein the cross-section of the tubular wire is circular, rectangular or square.

9. The device of Claim 1, wherein the device is a stent or graft formed from spirally-wound, tubular wire.

10. The device of Claim 9, wherein the device is a stent that is capable of being stressed prior to implantation to reduce the radius of curvature of the wire to put the stent in a restrained condition.

11. The device of Claim 1, wherein the tubular wire may contain one or more materials or fluids that improve the mechanical properties of the device.

12. The device of Claim 1, wherein the tubular wire may contain a pharmacological agent inside the lumen of the wire or on the outer surface of the wire.

13. The device of Claim 12, wherein the tubular wire has one or more openings to release the pharmacological agent.

14. The device of Claim 12, wherein the tubular wire has a multitude of miniature openings to permit slow diffusion of the pharmacological agent out of the lumen.

15. The device of Claim 1, wherein the tubular wire is partly or wholly radiopaque.

16. The device of Claim 1, wherein the tubular wire may contain radiopaque filler.

17. An implantable medical device comprised of hollow tubular wire, wherein the tubular wire has a hook or ball at each end.

FIG. 1

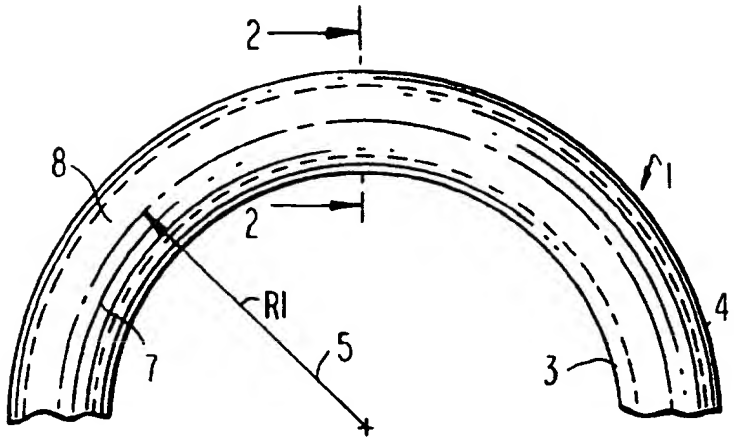



FIG. 2

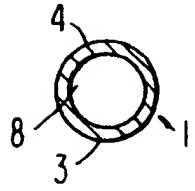
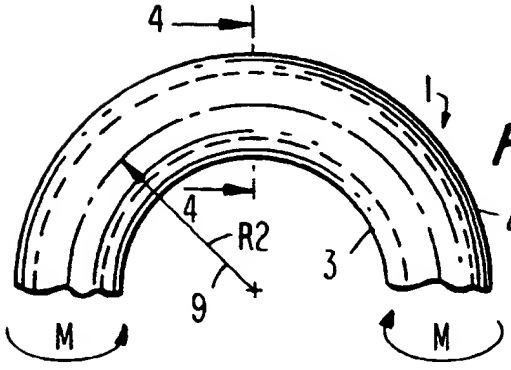



FIG. 3



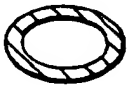



FIG. 4

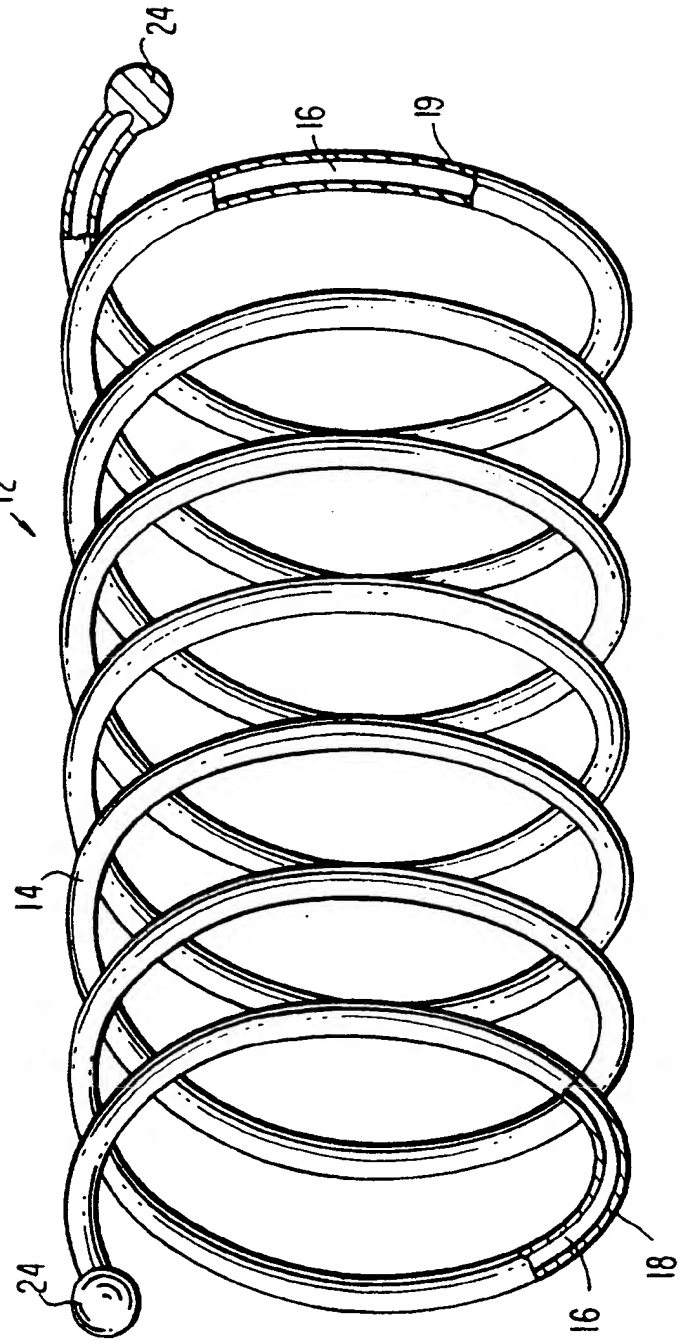



FIG. 5

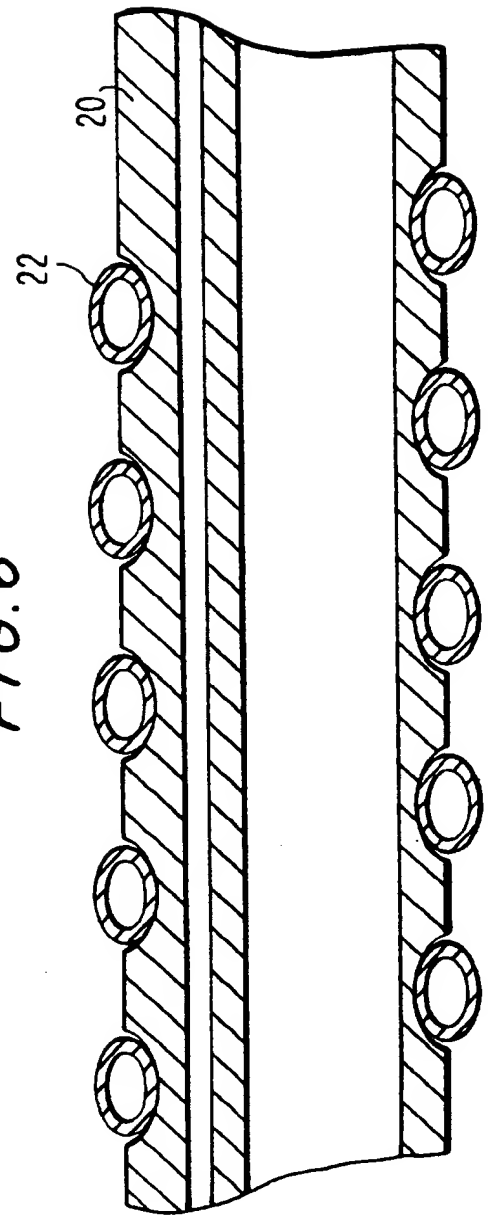



FIG. 6